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27777 7590 08/11/2008 PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003				
EXAMINER DEAK, LESLIE R				
ART UNIT 3761		PAPER NUMBER		
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/601,455

**Applicant(s)**

MEIR, ROSENBERG

**Examiner**

LESLIE R. DEAK

**Art Unit**

3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 June 2008.  
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-46 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 1-46 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
10) ☒ The drawing(s) filed on 25 January 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☐ Information Disclosure Statement(s) (PTO/5508)  
Paper No(s)/Mail Date \_\_\_\_\_  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_  
5) ☐ Notice of Informal Patent Application  
6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Claim Rejections - 35 USC § 112*

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 15-17 and 34-36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

35 U.S.C. 112, sixth paragraph states that a claim limitation expressed in means-plus- function language "shall be construed to cover the corresponding structure...described in the specification and equivalents thereof." "If one employs means plus function language in a claim, one must set forth in the specification an adequate disclosure showing what is meant by that language. If an applicant fails to set forth an adequate disclosure, the applicant has in effect failed to particularly point out and distinctly claim the invention as required by the second paragraph of section 112." See MPEP § 2181, citing In re Donaldson Co., 16 F.3d 1189, 1195, 29 USPQ2d 1845, 1850 (Fed. Cir. 1994) (in banc).

Applicant has failed to set forth what structure is meant by the "means for being...powered" in claims 15-17 and 34-36. Page 6 of applicant's specification provides a disclosure that the device may be powered by RF, acoustic, or optical

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waves, but discloses no structure capable of carrying out the powering function. Page 4, lines 4-7 of applicant's specification discloses that the apparatus comprises an antenna 28 for wireless communication with an external device, but does not set forth any apparatus that is capable of receiving power to the device. Therefore, the disclosure is not enabling for a "means for being...powered" by the various claimed power sources.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 15-17 and 34-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. The following guidance is provided to determine whether applicant has complied with the requirements of 35 U.S.C. 112, second paragraph, when 35 U.S.C. 112, sixth paragraph, is invoked:

- a. If the corresponding structure, material or acts are described in the specification in specific terms (e.g., an emitter-coupled voltage comparator) and one skilled in the art could identify the structure, material or acts from that description, then the requirements of 35 U.S.C. 112, second and sixth paragraphs are satisfied. See *Atmel*, 198 F.3d at 1382, 53 USPQ2d 1231.
- b. If the corresponding structure, material or acts are described in the specification in broad generic terms and the specific details of which are incorporated by reference to another document (e.g., attachment means disclosed in U.S. Patent No. X, which is hereby incorporated by reference, or a

comparator as disclosed in the IBM article, which is hereby incorporated by reference), Office personnel must review the description in the specification, without relying on any material from the incorporated document, and apply the "one skilled in the art" analysis to determine whether one skilled in the art could identify the corresponding structure (or material or acts) for performing the recited function to satisfy the definiteness requirement of 35 U.S.C. 112, second paragraph. See *Default Proof Credit Card System, Inc. v. Home Depot U.S.A., Inc.*, 412 F.3d 1291, 75 USPQ2d 1116 (Fed. Cir. 2005).

6. In the instant case, applicant's recitation of an antenna that communicates with an external device does not sufficiently disclose an apparatus that is capable of being powered by an external source, failing the first test. Applicant did not disclose the "means for" by incorporating any disclosure by reference, failing the second test. Accordingly, claims 15-17 and 34-36 are considered by the Examiner to be indefinite.

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1-24, 38-44, and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,585,677 to Cowan, Jr. et al in view of US 6,248,080 to Miesel et al.

In the specification and figures, Cowan discloses the device substantially as claimed by applicant. With regard to claims 1, 18, 19, 40, Cowan discloses an implantable medical device 20 comprising a housing 24, valve 50 disposed within the housing, a pressure sensor or valve-gauge assembly 52 disposed within the housing downstream of the valve, and a CPU or microprocessor associated with element 52 disposed within the housing and connected to the valve-gauge assembly 52. Cowan discloses that valve-gauge assembly 52 comprises a pressure sensor (indicating it is contained within housing 24) *and* a ventricular pressure gauge 52 (see FIG 1, columns 3-4, column 5, lines 11-20). Accordingly, Cowan teaches a valve and pressure sensor (valve-gauge assembly 52) disposed within the housing 24 downstream of valve 50.

Cowan fails to disclose a pressure sensor upstream of the valve within the housing. However, Miesel discloses an intracranial monitoring and therapy control device that may comprise several pressure sensors in and around a treatment device such as a valve in order to permit more accurate treatment of cerebral symptoms in a patient (see column 9, lines 20-67, column 11, lines 40-65). With that disclosure, Miesel suggests the addition of multiple pressure sensors around a treatment device in order to diagnose problems in the treatment apparatus, such as a catheter or valve blockage. Taken together, the references reasonably suggest to one of ordinary skill in the art an implantable medical device with pressure sensors disposed throughout the device that allow for accurate diagnosis and treatment of cerebral events, rendering the instantly claimed invention an unpatentably obvious variation of the prior art. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to

merely duplicate the pressure sensor arrangement 52 downstream of the valve as disclosed by Cowan to a location upstream of the valve 50 in order to diagnose valve performance.

With regard to claims 2-3, 9, the CPU or valve-gauge assembly with processing unit 52 disclosed by Cowan is electrically connected to the pressure sensors (see columns 5-6, FIG 1). The valve-gauge assembly is connected to transmitter 64 that transmits information to an external computing device (see column 6, lines 1-15).

With regard to claims 4, 5, 10, and 14, applicant claims that the CPU comprises a "means for calculating" a particular parameter. A claim limitation will be interpreted to invoke 35 U.S.C. 112, sixth paragraph, if it meets the following 3-prong analysis (see MPEP § 2181):

- c. the claim limitations must use the phrase "means for" or "step for;"
- d. the "means for" or "step for" must be modified by functional language;  
and
- e. the phrase "means for" or "step for" must not be modified by sufficient structure, material or acts for achieving the specified function.

In the instant case, applicant has satisfied all three prongs of the test and the Examiner has turned to the specification for clarification.

35 U.S.C. 112, sixth paragraph states that a claim limitation expressed in means-plus-function language "shall be construed to cover the corresponding structure... described in the specification and equivalents thereof." See MPEP 2181(II). In paragraph 0008 of US 2004/0260229, applicant discloses that the CPU compares

values generated by the pressure sensors to generate a differential pressure. It is the position of the Examiner that this disclosure indicates that the "means for calculating" comprises a programmed algorithm. Cowan discloses that the valve-gauge assembly 52 comprises a microprocessor that receives input from the pressures sensors 52, 54 and is programmed with various criteria to determine whether the valve should be opened or closed (see column 5, lines 11-26). Such programs are considered by the Examiner to be functional equivalents of the algorithm disclosed by applicant, since differential pressure values are known in the art to control valve movement. Accordingly, the disclosure of Cowan suggests the apparatus of applicant's claims 4, 5, 10, and 14.

With regard to claims 6-8, Cowan discloses a first catheter 28 fluidly connected to housing 24 upstream of valve 50 with a pressure sensor 54 disposed within the catheter 34 and connected to the CPU or valve-gauge assembly 52 (see FIG 1).

With regard to claims 11-13, Cowan discloses a catheter 32 fluidly connected to housing 24 downstream of valve 50. Cowan fails to disclose a fourth pressure sensor on second catheter 32. However, Miesel discloses an intracranial monitoring and therapy control device that may comprise several pressure sensors in and around a treatment device such as a valve in order to permit more accurate treatment of cerebral symptoms in a patient (see column 9, lines 20-67, column 11, lines 40-65). With that disclosure, Miesel suggests the addition of multiple pressure sensors around a treatment device in order to diagnose problems in the treatment apparatus, such as a catheter or valve blockage. Taken together, the references reasonably suggest to one of ordinary skill in the art an implantable medical device with pressure sensors



disposed throughout the device that allow for accurate diagnosis and treatment of cerebral events, rendering the instantly claimed invention an unpatentably obvious variation of the prior art. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to merely duplicate the pressure sensor arrangement on the first catheter 28 disclosed by Cowan on the second catheter 32 in order to diagnose blockages throughout the system.

With regard to claims 15-17, applicant claims that the CPU comprises a "means for being...powered" with a particular technology. In the interest of compact prosecution, Examiner is addressing the claims on their merits, despite the 35 USC 112 rejections presented above. A claim limitation will be interpreted to invoke 35 U.S.C. 112, sixth paragraph, if it meets the following 3-prong analysis (see MPEP § 2181):

- a. the claim limitations must use the phrase "means for" or "step for;"
- b. the "means for" or "step for" must be modified by functional language;  
and
- c. the phrase "means for" or "step for" must not be modified by sufficient structure, material or acts for achieving the specified function.

In the instant case, applicant has satisfied all three prongs of the test and the Examiner has turned to the specification for clarification.

35 U.S.C. 112, sixth paragraph states that a claim limitation expressed in means-plus-function language "shall be construed to cover the corresponding structure... described in the specification and equivalents thereof." Page 4, lines 4-7 of applicant's specification discloses that the apparatus comprises an antenna 28 for wireless

communication with an external device. Cowan discloses that his apparatus comprises a transmitter 64 for communicating with an external receiver, which the Examiner considers to be a functional equivalent to applicant's antenna. Accordingly, claims are unpatentable over the prior art.

With regard to claim 20, Cowan and Meisel fail to disclose that the CPU is located outside the housing 24. It has been held that mere rearrangement of the parts of a device found in the prior art is within the skill of a worker in the art, especially if the device with the instantly claimed arrangement would not perform differently than the prior art device. See MPEP 2144.04(IV)(B). In the instant case, applicant has not stated that the location of the CPU outside the housing is for any particular purpose or solves any particular problem. It is the position of the Examiner that the location of the CPU does not affect the performance of the device either as suggested by the prior art or as claimed by applicant. Accordingly, the claimed apparatus is unpatentable over the prior art of record.

With regard to claims 21, 24, 38, and 39, Cowan discloses a first pressure sensor 54 upstream of the valve 50. Cowan also discloses that the valve-gauge assembly 52 comprises a microprocessor that receives input from the pressures sensors 52 (contained entirely within the housing), 54 and is programmed with various criteria to determine whether the valve should be opened or closed (see column 5, lines 11-26) and may wirelessly transmit data to an external device (see column 6, lines 1-15). Cowan fails to disclose a pressure sensor upstream of the valve within the housing. However, Miesel discloses an intracranial monitoring and therapy control device that

may comprise several pressure sensors in and around a treatment device such as a valve in order to permit more accurate treatment of cerebral symptoms in a patient (see column 9, lines 20-67, column 11, lines 40-65). With that disclosure, Miesel suggests the addition of multiple pressure sensors around a treatment device in order to diagnose problems in the treatment apparatus, such as a catheter or valve blockage. Taken together, the references reasonably suggest to one of ordinary skill in the art an implantable medical device with pressure sensors disposed throughout the device that allow for accurate diagnosis and treatment of cerebral events, rendering the instantly claimed invention an unpatentably obvious variation of the prior art. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to merely duplicate the pressure sensor arrangement 52 downstream of the valve as disclosed by Cowan to a location upstream of the valve 50 in order to diagnose valve performance using the programmed CPU and wireless communication disclosed by Cowan.

With regard to claims 22-23, Cowan discloses a catheter 32 fluidly connected to housing 24 downstream of valve 50. Cowan discloses that the valve-gauge assembly 52 comprises a microprocessor that receives input from the pressures sensors 52, 54 and is programmed with various criteria to determine whether the valve should be opened or closed (see column 5, lines 11-26) and may wirelessly transmit data to an external device (see column 6, lines 1-15). Cowan fails to disclose a fourth pressure sensor on second catheter 32. However, However, Miesel discloses an intracranial monitoring and therapy control device that may comprise several pressure sensors in

and around a treatment device such as a valve in order to permit more accurate treatment of cerebral symptoms in a patient (see column 9, lines 20-67, column 11, lines 40-65). With that disclosure, Miesel suggests the addition of multiple pressure sensors around a treatment device in order to diagnose problems in the treatment apparatus, such as a catheter or valve blockage. Taken together, the references reasonably suggest to one of ordinary skill in the art an implantable medical device with pressure sensors disposed throughout the device that allow for accurate diagnosis and treatment of cerebral events, rendering the instantly claimed invention an unpatentably obvious variation of the prior art. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to merely duplicate the pressure sensor arrangement on the first catheter 28 disclosed by Cowan on the second catheter 32 in order to diagnose blockages throughout the system.

With regard to claims 41-44 and 46, Cowan and Miesel suggest the apparatus as claimed with the exception of the components disposed on the same substrate. Applicant has not shown that the location of the components on the same substrate is for any particular purpose or solves any particular problem. It is the position of the Examiner that the location of the components on the same substrate does not affect the performance of the device either as suggested by the prior art or as claimed by applicant. Accordingly, the claimed apparatus is unpatentable over the prior art of record.

9. Claims 25-30 and 34-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,585,677 to Cowan, Jr. et al in view of US 4,206,762 to Cosman.

In the specification and figures, Cowan discloses the apparatus and method substantially as claimed by applicant. With regard to claim 25, Cowan discloses an implantable medical device 20 comprising a housing 24, valve 50 disposed within the housing, a pressure sensor 52 disposed within the housing downstream of the valve, and a microprocessor associated with element 52 disposed within the housing and connected to the pressure sensor (see FIG 1, columns 3-4).

Cowan fails to disclose that the pressure sensor 52 comprises a differential pressure sensor. However, Cosman discloses an implantable differential pressure sensor that upon undergoing a conformational change, transmits that information to an external device. The device allows for the accurate measurement of a difference in pressure across a membrane (see columns 1-2). The combination of the shunt apparatus disclosed by Cowan with the differential pressure sensor disclosed by Cosman by known methods yields only predictable results—that is, a shunt system that relies on a single sensor, rather than two sensors, to generate a differential pressure measurement to operate an associated shunt valve. Accordingly, it is the position of the Examiner that taken together, the references reasonably suggest the claimed invention to a person of ordinary skill in the art.

With regard to claim 26, both Cowan and Cosman disclose that the apparatus is connected to an apparatus that transmits information to an external computing device (see Cowan column 6, lines 1-15, Cosman column 1, lines 13-24).

With regard to claims 27-30, Cowan discloses a first catheter 28 fluidly connected to housing 24 upstream of valve 50 with a pressure sensor 54 disposed within the catheter 34 and connected to the CPU or valve-gauge assembly 52 (see FIG 1).

With regard to claims 34-36, applicant claims that the CPU comprises a "means for being...powered" with a particular technology. In the interest of compact prosecution, Examiner is addressing the claims on their merits, despite the 35 USC 112 rejections presented above. A claim limitation will be interpreted to invoke 35 U.S.C. 112, sixth paragraph, if it meets the following 3-prong analysis (see MPEP § 2181):

- d. the claim limitations must use the phrase "means for" or "step for;"
- e. the "means for" or "step for" must be modified by functional language;  
and
- f. the phrase "means for" or "step for" must not be modified by sufficient structure, material or acts for achieving the specified function.

In the instant case, applicant has satisfied all three prongs of the test and the Examiner has turned to the specification for clarification.

35 U.S.C. 112, sixth paragraph states that a claim limitation expressed in means-plus-function language "shall be construed to cover the corresponding structure...described in the specification and equivalents thereof." Page 4, lines 4-7 of applicant's specification discloses that the apparatus comprises an antenna 28 for wireless communication with an external device. Cowan discloses that his apparatus comprises a transmitter 64 for communicating with an external receiver, which the Examiner

considers to be a functional equivalent to applicant's antenna. Accordingly, claims are unpatentable over the prior art.

With regard to claim 37, Cowan discloses that the valve-gauge assembly 52 comprises a microprocessor that receives input from the pressure sensors and is programmed with various criteria to determine whether the valve should be opened or closed (see column 5, lines 11-26) and may wirelessly transmit data to an external device (see column 6, lines 1-15). The combination of the method disclosed by Cowan with the differential pressure sensor disclosed by Cosman by known methods yields only predictable results—that is, a shunt system and method that relies on a single sensor, rather than two sensors, to generate a differential pressure measurement to operate an associated shunt valve. Accordingly, it is the position of the Examiner that taken together, the references reasonably suggest the claimed invention to a person of ordinary skill in the art.

With regard to claim 45, Cowan and Cosman suggest the apparatus as claimed with the exception of the components disposed on the same substrate. Applicant has not shown that the location of the components on the same substrate is for any particular purpose or solves any particular problem. It is the position of the Examiner that the location of the components on the same substrate does not affect the performance of the device either as suggested by the prior art or as claimed by applicant. Accordingly, the claimed apparatus is unpatentable over the prior art of record.

10. Claims 31-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,585,677 to Cowan, Jr. et al in view of US 4,206,762 to Cosman, further in view of US 6,428,080 to Miesel.

In the specification and figures, Cowan and Cosman suggest the apparatus substantially as claimed by applicant (see rejection above) with the exception of an additional pressure sensor located on a second catheter. With regard to claims 11-13, Cowan discloses a catheter 32 fluidly connected to housing 24 downstream of valve 50. Cowan fails to disclose a fourth pressure sensor on second catheter 32.

However, Miesel discloses an intracranial monitoring and therapy control device that may comprise several pressure sensors in and around a treatment device such as a valve in order to permit more accurate treatment of cerebral symptoms in a patient (see column 9, lines 20-67, column 11, lines 40-65). With that disclosure, Miesel suggests the addition of multiple pressure sensors around a treatment device in order to diagnose problems in the treatment apparatus, such as a catheter or valve blockage. Taken together, the references reasonably suggest to one of ordinary skill in the art an implantable medical device with pressure sensors disposed throughout the device that allow for accurate diagnosis and treatment of cerebral events, rendering the instantly claimed invention an unpatentably obvious variation of the prior art. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to merely duplicate the pressure sensor arrangement on the first catheter 28 disclosed by Cowan on the second catheter 32 in the apparatus suggested by Cowan and Cosman in order to diagnose blockages throughout the system.



***Response to Arguments***

11. Applicant's arguments filed 5 June 2008 have been entered and fully considered
12. Applicant's arguments with regard to the 35 USC 112 rejections of claims 15-17 and 34-36 have been fully considered but they are not persuasive.

Applicant argues that the specification enables the claim language by references to the knowledge of one of ordinary skill in the relevant art and cites several patents intended to show what the level of skill in the art is.

However, Applicant has essentially admitted that the specification does not disclose the intended structure for powering as in response he has simply pointed to a variety of other patents that use RF telemetry. Even a casual review of the cited patents show that there is no single specific structure that provides that type of power source. While some of the cited references contain structures that are similar to that envisioned by Applicant, the actual structure intended is not clear.

The Examiner recognizes that: "The disclosure of the structure (or material or acts) may be implicit or inherent in the specification if it would have been clear to those skilled in the art what structure (or material or acts) corresponds to the means (or step)-plus-function claim limitation. See *Id.* at 1380, 53 USPQ2d at 1229; *In re Dossel*, 115 F.3d 942, 946-47, 42 USPQ2d 1881, 1885 (Fed. Cir. 1997) (MPEP § 2181 (II)). However, in this case, the variable structure of the very references cited by the applicant indicates that a specific structure cannot be identified.

Applicant further argues that RF telemetry, optical, and acoustical powering methods and structures are known in the art. However, "[a] bare statement that known

techniques or methods can be used does not disclose structure” in the context of a means plus function limitation. *Biomedino, LLC v. Waters Technology Corp.*, 490 F.3d 946, 952, 83 USPQ2d 1118, 1123 (Fed. Cir. 2007) (Disclosure that an invention “may be controlled by known differential pressure, valving and control equipment” was not a disclosure of any structure corresponding to the claimed “control means for operating [a] valving” and the claim was held indefinite.) (MPEP § 2181 (II)).

While a variety of structural elements may be used to provide the type of power intended are known in the art, as Applicant has invoked 35 U.S.C. § 112, 6th paragraph analysis, the specific structure intended must be disclosed. Even after reading the response the question remains, what structure is the claim limitation pointing to?

13. Applicant’s arguments with regard to the combination of Cowan and Miesel have been fully considered but are not persuasive.

Applicant argues that Cowan’s combination of a valve-gauge assembly 52 within housing 24 connected to gauge 54 in the ventricle, or outside the housing, does not teach or suggest a valve and pressure sensor disposed within the housing. However, as pointed out above, Cowan’s valve-gauge assembly 52 comprises a valve and a pressure gauge *and also includes* pressure gauge 54 (see column 5, lines 11-20). Accordingly, Cowan does, in fact, disclose a valve and pressure sensor or gauge disposed within the housing. While Cowan teaches that a second pressure gauge 54 is located outside the housing, such a disclosure does not teach away from including a second assembly within the housing, upstream of the valve. Combined with the Miesel disclosure of using several pressure sensors along the length of the catheter, one of

ordinary skill in the art would have been motivated to add a second pressure gauge in order to monitor the performance of the valve between the gauges.

14. Applicant argues that the battery power disclosed by Cowan and Miesel does not constitute a non-invasive power source. The Examiner respectfully disagrees. Applicant does not define a non-invasive power source except to explain that the device may be powered by some telemetry, which relies on an antenna. Since applicant provides no special definition of "non-invasively powered," it is the position of the Examiner that the batteries used by the disclosed apparatus are non-invasive, and that the disclosed apparatuses are capable of communicating with external devices via the disclosed antenna.

15. Applicant argues that the differential pressure sensor disclosed by Cosman cannot function in the modified Cowan device, since a differential pressure sensor requires access to CSF to function. The Examiner respectfully disagrees. A differential pressure sensor may be placed anywhere on the catheter, as illustrated in FIG 11 of Cosman. Furthermore, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). In the instant case, the cited prior art, taken together as a whole, suggests the use of differential pressure sensors in a cerebrospinal fluid

shunt and catheter, which may be incorporated in a housing at a particular location on the catheter.

### ***Conclusion***

16. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **LESLIE R. DEAK** whose telephone number is (571)272-4943. The examiner can normally be reached on Monday - Friday, 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leslie R. Deak/  
Primary Examiner  
Art Unit 3761  
4 August 2008